



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0744; FRL-10769-01-OCSP]

Fludioxonil; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation modifies existing tolerances for residues of fludioxonil in or on mango and papaya. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0744, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Daniel Rosenblatt, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180?toc=1>.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0744 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE

FEDERAL REGISTER]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0744, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of October 24, 2022 (87 FR 64196) (FRL-9410-06-OCSP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8947) by Syngenta Crop Protection, LLC, 410 Swing Road, Greensboro, NC 27409. The petition requested that 40 CFR 180.516 be amended by establishing import tolerances for residues of the fungicide fludioxonil, [4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile], in or on mango at 15 parts per million (ppm) and papaya at 8 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <https://www.regulations.gov>.

There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition and in accordance with its authority under FFDCA section 408(d)(4)(A)(i), EPA is modifying the existing tolerances for residues of fludioxonil in or on mango and papaya at different levels than requested. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fludioxonil, including exposure resulting from the tolerances modified by this action. EPA's assessment of exposures and risks associated with fludioxonil follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections of the rule that repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the

information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for fludioxonil in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fludioxonil and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rule, as they remain unchanged.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Specific information on the studies received and the nature of the adverse effects caused by fludioxonil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in Unit III.A. of the final rule published in the *Federal Register* of November 6, 2018 (83 FR 55491) (FRL-9982-75).

B. Toxicological Points of Departure/Levels of Concern

A summary of the toxicological endpoints for fludioxonil used for human health risk assessment is discussed in Unit III.B. of the final rule published in the *Federal Register* of August 14, 2015 (80 FR 48743) (FRL-9931-06).

C. Exposure Assessment

Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from the petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the November 6, 2018, rulemaking.

1. *Dietary exposure from food and feed uses.* EPA's dietary exposure assessments have

been updated to include the additional exposure from the petitioned-for tolerances for residues of fludioxonil on mango and papaya. An acute dietary risk assessment was not performed since no endpoint attributable to a single exposure (dose) was identified from the available oral toxicity database. The chronic assessment is based on tolerance-level residues and assumes 100 percent crop treated (PCT); the chronic assessment is unrefined. The assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), Version 4.02, which incorporates 2005-2010 food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). A cancer dietary exposure and risk assessment was not conducted for fludioxonil as it is a Group D chemical - not classifiable as to human carcinogenicity.

2. *Dietary exposure from drinking water.* The proposed post-harvest application uses on imported fruit do not result in an increase in the estimated residue levels in drinking water, so the estimated drinking water concentrations used in the November 6, 2018, final rule are the same as those used in this assessment.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). The assessment used the same assumptions as the November 6, 2018. The residential exposures used in the aggregate assessment are inhalation exposures from handlers applying paints with airless sprayers for adults and incidental oral exposures (hand-to-mouth) from post-application exposure to outdoor treated turf for children 1 to <2 years old.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, leave in effect, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common

mechanism of toxicity.”

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fludioxonil and any other substances, and fludioxonil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fludioxonil has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the November 6, 2018, rulemaking for a discussion of the Agency’s rationale for that determination.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure (PODs) to ensure that an adequate margin of exposure (MOE) exists.

An acute dietary exposure assessment was not performed as there were no indication of an adverse effects attributable to a single dose. Fludioxonil is not expected to pose an acute risk. Chronic dietary risks are below the Agency’s level of concern of 100% of the cPAD; they are 14% of the cPAD for the general population and 49% of the cPAD for children 1-2 years old, the population subgroup receiving the highest exposure.

EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1200 for adults and 290 for children 1-2 years old. Because EPA’s level of

concern for fludioxonil is an MOE of 100 or below, short-term aggregate risks are not of concern. Intermediate- and long-term aggregate risk assessments were not performed because there are no registered or proposed uses of fludioxonil that result in intermediate- or long-term residential exposures. Fludioxonil is not classifiable as to human carcinogenicity; therefore, EPA does not expect exposures to pose an aggregate cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to fludioxonil residues. More detailed information on this action can be found in the document titled “Fludioxonil. Human Health Risk Assessment for the Proposed Tolerances without a U.S. Registration for Residues of Fludioxonil in/on Mango and Papaya.” in docket ID number EPA-HQ-OPP-2021-0744.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the November 6, 2018, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There is no Codex MRL for fludioxonil in or on papaya. Canada has established an MRL for fludioxonil in or on papaya at 5 ppm, which is the same as the U.S. tolerance as modified by this action. Codex and Canada have established MRLs for fludioxonil in or on mango at 2 ppm. These MRLs are different than the U.S. tolerance as modified by this action, which is 8 ppm for fludioxonil residues in or on mango. EPA is not harmonizing the U.S. tolerance with the Codex

and Canadian MRLs because the proposed post-harvest application use on fruit imported into the United States results in residues greater than 2 ppm. The increased tolerance of 8 ppm is needed to cover residues resulting from post-harvest application to imported fruit and would not affect trade channels with Canada or the European Union.

C. Revisions to Petitioned-For Tolerances

The registrant petitioned for import tolerances of 15 ppm for mango and 8 ppm for papaya. However, EPA has previously established tolerances for residues of fludioxonil in or on mango and papaya, both at 5.0 ppm, at 40 CFR 180.516. In this action, EPA is modifying these established tolerances by increasing the tolerance for mango to 8 ppm and revising the tolerance for papaya to 5 ppm based on the submitted field trial data, Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures, and rounding rules. These tolerances are inclusive of imported commodities as well as domestically produced.

V. Conclusion

Therefore, tolerances are modified for residues of fludioxonil, [4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile], in or on mango at 8 ppm and papaya at 5 ppm.

VI. Statutory and Executive Order Reviews

This action modified tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations

under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act (CRA)

Pursuant to the CRA (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 16, 2023.

Daniel Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180-- TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.516, revise the commodities “mango” and “papaya” in the table in paragraph (a)(1) to read as follows:

§180.516 Fludioxonil; tolerances for residues.

* * * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * * *	
Mango	8
* * * * *	
Papaya	5
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